

Remarks

This Amendment is being filed in response to two Office Actions dated August 25, 2004 and October 1, 2004. The Office Actions appear to be identical. Applicants are filing a Petition for One Month Extension of Time which is attached hereto, because this Amendment is being filed after November 25, 2004 but before December 27, 2004, and Applicants are using the due dates for the earlier dated Office Action.

Applicants request that the Examiner, in the next Communication, acknowledge that Applicants have responded to both Office Actions.

Objections to Specification

The Examiner raised several objections in the Specification.

First, the Examiner requested that Applicants add "SEQ ID NO:1" after the DNA sequence that appears on page 4, lines 8-27. Applicants requested this correction in the Preliminary Amendment; it was the last item in the Amendment to Specification section of the Preliminary Amendment. However, to ensure that this correction is entered into the record, the Applicants are making the correction again.

The Examiner also objected to the misspelling of *Renibacterium salmoninarium* on page 1, line 4. Applicants are requesting the correction in this Amendment.

The Examiner requested that Applicants add the phrase "now U.S. Patent No. 6,627,203" to the priority claim in line 1 of page 1. Applicants are requesting this correction in this Amendment.

Applicants request that the Examiner withdraw the objections to the Specification.

Other Amendments to Specification

Applicants noticed three other typographical errors on pages 1, 6, and 7 in the Specification and are requesting the amendments indicated above. The changes do not add new matter.

Amendments to Claims

Applicants are canceling Claims 20-23.

Applicants are requesting the amendment of Claims 8-19. These amendments, which are discussed in full below, do not add new matter.

35 U.S.C. §112, second paragraph

The Examiner rejected Claims 9, 11, 13, 15, 17, 19, 21 and 23 under 35 U.S.C. §112, second paragraph as being vague and indefinite because it is unclear whether the adjuvant is co-administered with the dose of *Arthrobacter* or at a separate time. The Examiner also requested that the genus/species names in the claims be italicized.

Applicants have amended Claims 9, 11, 13, 15, 17, and 19 to indicate that the adjuvant is being administered with the *Arthrobacter*. Claims 21 and 23 are cancelled. Applicants believe that these amendments and cancellation overcome the Examiner's rejection and request that the withdrawal of this rejection.

Applicants have amended any pending claims containing a genus/species name to italicize the genus/species name. Applicants request the withdrawal of this rejection.

35 U.S.C. §112, first paragraph (enablement)

The Examiner rejected Claims 8-23 under 35 U.S.C. §112, first paragraph as being not enabled.

In Paragraph 7, the Examiner stated that the specification is enabling for "a method of inducing an immune response against *Renibacterium salmoninarum* in fish comprising administering an effective immunizing dose of *Arthrobacter* strain RSxII to said fish." The Examiner feels that the specification does not enable using any species of *Arthrobacter*.

Applicants note that, as amended, independent Claim 8 is for a method of inducing an immune response against *Renibacterium salmoninarum* in fish comprising administering an effective immunizing dose of *Arthrobacter* strain RSxII to said fish. Claim 8 is being amended to limit the *Arthrobacter* species used to *Arthrobacter* strain RSxII.

Claims 9, 10, and 11 are dependent on Claim 8 and thus are not any broader than Claim 8. The amendments to Claim 9 and 11, as discussed above, indicate that the adjuvant is administered concurrently with the bacteria. The amendment to Claim 10 is made to italicize the genus name of *Arthrobacter*. Applicants note that Claim 10 as filed in the Preliminary Amendment was limited to the *Arthrobacter* strain RSxII which was deposited with ATCC and assigned deposit number ATCC 55921.

Thus, Applicants believe that Examiner's rejection under §112, first paragraph of Claims 8-11 are now moot and requests that the Examiner withdraw this rejection of Claims 8-11.

Also in Paragraph 7, the Examiner stated that the specification is enabled for a "method of immunizing a fish to a disease caused by *Renibacterium salmoninarum* in fish comprising

administering an effective immunizing dose of *Arthrobacter* strain RSxII to said fish." The Examiner feels that the specification does not enable using any species of *Arthrobacter*.

Applicants would like to point out that independent Claim 12 is for a method of immunizing a fish to a disease caused by *Renibacterium salmoninarum* by administering an effective immunizing dose of *Arthrobacter* strain RSxII to the fish. Claim 12 has been amended to limit the claim to using *Arthrobacter* strain RSxII to immunize the fish.

Claims 13, 14, and 15 are dependent on Claim 12 and thus do not extend beyond the scope of Claim 12. The amendments to Claim 13 and 15, as discussed above, indicate that the adjuvant is administered concurrently with the bacteria. The amendment to Claim 14 is made to italicize the genus name of *Arthrobacter*. Applicants note that Claim 14 as filed in the Preliminary Amendment was limited to the *Arthrobacter* strain RSxII which was deposited with ATCC and assigned deposit number ATCC 55921.

Thus, Applicants believe that Examiner's rejection under §112, first paragraph of Claims 12-15 are now moot and requests that the Examiner withdraw this rejection of Claims 12-15.

In Paragraph 7, the Examiner rejected Claims 16-19 under § 112, first paragraph because the Examiner feels that the specification does not enable "a method for preventing the occurrence of bacterial kidney disease in fish comprising administering an effective amount of *Arthrobacter* strain RSxII or *Arthrobacter* to said fish".

Applicants point out that independent Claim 16 has been amended to administering *Arthrobacter* strain RSxII. Claims 17-19 are dependent on Claim 16 and thus are not broader than the scope of Claim 16. Again, Claims 17 and 19 are amended to indicate that the adjuvant is administered with the bacteria. Claim 18 has been amended to italicize the genus *Arthrobacter*.

Turning now to the preamble for Claims 16-19 ("a method for preventing the occurrence of bacterial kidney disease in fish"), it is well-known to one skilled in the art that *Renibacterium salmoninarum* is the causative agent of bacterial kidney disease in fish. This fact is referred to in the Specification on page 1, lines 9-14 where it states that the invention protects "farmed fish against a disease caused by ... *Renibacterium salmoninarum*. This disease is colloquially named bacterial kidney disease..." According to the Examiner, the Specification enables the "inducing of an immune response" in fish against *Renibacterium salmoninarum* and "immunizing fish to a disease caused by *Renibacterium salmoninarum*." The disease to which the fish are immunized is bacterial kidney disease. By inducing an immune response in fish to *Renibacterium salmoninarum* one protects the fish against *Renibacterium salmoninarum* and the disease that it causes, namely bacterial kidney disease. If one can prevent the treated fish from being infected with *Renibacterium salmoninarum* then one can prevent the occurrence of bacterial kidney disease in the fish so treated. Thus, Applicants believe that Claims 16-19, as

amended, are clearly enabled in the Specification and requests that the Examiner withdraw this rejection for these claims.

The Examiner also rejected Claims 20-23 in Paragraph 7 under § 112, first paragraph as not being enabled in the specification.

Applicants have cancelled Claims 20-23 and thus this rejection is moot.

35 U.S.C. § 112, first paragraph (written description)

In Paragraph 8, the Examiner rejected Claims 16-23 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner feels that the Specification lacks a written description for a “method for treating bacterial kidney disease in fish” (Claims 20-23) and a “method for preventing the occurrence of bacterial kidney disease in fish” (Claims 16-19). The Examiner feels that the Specification does, however, provide a written description for “a method for protecting against a disease caused by *Renibacterium salmoninarum*” and a “method of inducing an immune response against *Renibacterium salmoninarum*.”

While it is true that the Specification does not state the words “a method for preventing the occurrence of bacterial kidney disease in fish” (for Claims 16-19), the Specification does indicate that bacterial kidney disease is caused by *Renibacterium salmoninarum* (see page 1, lines 9-14). Furthermore, if the Specification clearly contains enough of a written description for protecting against a disease caused by *Renibacterium salmoninarum*, and that disease is known, and stated, to be bacterial kidney disease, then the Specification contains enough of a written description for a method for preventing the occurrence of bacterial kidney disease in fish”. It is not necessary for the Specification to contain every word of the claim so long as it is well-known in the art that what is taught in the Specification relates to the metes and bounds of the claims. Claims 16-19 are clearly taught by the Specification and satisfy the written description requirement. Applicants request that the Examiner withdraw this rejection to Claims 16-19.

Applicants have cancelled Claims 20-23, making this part of the Examiner’s rejection moot.

Applicants believe that Claims 8-19 are allowable and requests that the Examiner allow the claims.

The Commissioner is hereby authorized to charge any fees which may be required to maintain the pendency of this patent application to Account No. 19-0134 in the name of Novartis.

If it would assist in moving the pending claims to allowance, the Examiner is invited to contact the undersigned at the number indicated below.

Respectfully submitted,

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